

Serial No. 10/766,172  
Page 2 of 11

Docket No. INSC-109.4

**AMENDMENT TO CLAIMS:**

1. (Original) A thermoplastic stopper defining a needle penetration region that is pierceable with a needle to form a needle aperture therethrough, and is heat resealable to hermetically seal the needle aperture by applying laser radiation at a predetermined wavelength and power thereto, wherein the stopper comprises a thermoplastic body defining a predetermined wall thickness in an axial direction thereof, and including (i) a styrene block copolymer; (ii) an olefin; (iii) a predetermined amount of pigment that allows the body to substantially absorb laser radiation at the predetermined wavelength and substantially prevent the passage of radiation through the predetermined wall thickness thereof, and hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period of less than approximately 2 seconds; and (iv) a predetermined amount of lubricant that reduces friction forces at an interface of the needle and body during needle penetration thereof.
2. (Original) A stopper as defined in claim 1, wherein the styrene block copolymer is within the range of about 80% to about 97% by weight.
3. (Original) A stopper as defined in claim 1, wherein the olefin is within the range of about 3% to about 20% by weight.
4. (Original) A stopper as defined in claim 1, wherein the body includes about 90% by weight styrene block copolymer and about 5% by weight olefin.

Serial No. 10/766,172  
Page 3 of 11

Docket No. INSC-109.4

5. (Original) A stopper as defined in claim 1, wherein the ratio of the styrene block copolymer to the olefin are within the range of about 50 : 50 by weight to about 90:5 by weight.

6. (Original) A stopper as defined in claim 1, wherein the predetermined wavelength is approximately 980 nm.

7. (Original) A stopper as defined in claim 1, wherein the predetermined power is less than approximately 30 Watts.

8. (Original) A stopper as defined in claim 7, wherein the predetermined power is less than or equal to about 10 Watts.

9. (Original) A stopper as defined in claim 1, wherein the pigment is gray.

10. (Original) A stopper as defined in claim 8, wherein the amount of pigment is within the range of about 0.3% to about 0.6% by weight.

11. (Original) A stopper as defined in claim 1, wherein the predetermined time period is less than about 1.5 seconds.

12. (Original) A stopper as defined in claim 1, wherein the stopper is a vial stopper.

Serial No. 10/766,172  
Page 4 of 11

Docket No. INSC-109.4

13. (Original) A stopper as defined in claim 1, wherein the stopper is in the form of a syringe plunger.

14. (Original) A stopper as defined in claim 1, wherein the lubricant is selected from the group including silicone, mineral oil, and silicone oil.

15. (Original) A stopper as defined in claim 1, wherein the lubricant is silicone oil and the amount of lubricant is within the range of about 0.4 to about 0.6% by weight.

16. (Original) A stopper as defined in claim 1, in combination with a needle for penetrating the stopper, wherein the needle includes a non-coring, conically-pointed tip defining an included angle within the range of about 15 degrees to about 25 degrees.

17. (Original) A stopper and needle as defined in claim 16, wherein the needle includes a low-friction coating for reducing friction forces between the needle and stopper during penetration thereof.

18. (Original) A stopper and needle as defined in claim 17, wherein the low-friction coating is selected from the group including tungsten carbide and titanium.

19. (Original) A thermoplastic stopper defining a needle penetration region that is pierceable with a needle to form a needle aperture therethrough, and is heat resealable to hermetically seal the needle aperture by applying laser radiation at a predetermined wavelength

Serial No. 10/766,172  
Page 5 of 11

Docket No. INSC-109.4

and power thereto, wherein the stopper comprises a thermoplastic body defining a predetermined wall thickness in an axial direction thereof, and including (i) a first polymeric material in an amount within the range of about 80% to about 97% by weight and defining a first elongation; (ii) a second polymeric material in an amount within the range of about 3% to about 20% by weight and defining a second elongation that is less than the first elongation of the first material; (iii) a pigment in an amount that allows the body to substantially absorb laser radiation at the predetermined wavelength and substantially prevent the passage of radiation through the predetermined wall thickness thereof, and hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period of less than approximately 2 seconds; and (iv) a lubricant in an amount that reduces friction forces at an interface of the needle and body during needle penetration thereof.

20. (Original) A stopper as defined in claim 19, wherein the first material defines a higher melting temperature than the second material.

21. (Original) A stopper as defined in claim 20, wherein the first material is a styrene block copolymer and the second material is an olefin.

22. (Original) A stopper as defined in claim 19, wherein the first material defines a first elongation of at least about 75% at about 10 lbs force.

23. (Original) A stopper as defined in claim 22, wherein the first material defines a first elongation within the range of about 85% to at least about 90% at about 10 lbs force.

Serial No. 10/766,172  
Page 6 of 11

Docket No. INSC-109.4

24. (Original) A stopper as defined in claim 19, wherein the second material defines a second elongation of at least about 5% at about 10 lbs force.

25. (Original) A stopper as defined in claim 24, wherein the second material defines a second elongation within the range of about 15% to about 25% at about 10 lbs force.

26. (Original) A stopper as defined in claim 19, wherein the first material is a styrene block copolymer.

27. (Original) A stopper as defined in claim 19, wherein the second material is an olefin.

28. (Original) A stopper as defined in claim 1, wherein the first material is a styrene block copolymer, the second material is an olefin, and the body includes about 90% by weight styrene block copolymer and about 5% by weight olefin.

29. (Original) A stopper as defined in claim 19, wherein the first material is a styrene block copolymer, the second material is an olefin, and the ratio of the styrene block copolymer to the olefin is about 90:5 by weight.

30. (Original) A stopper as defined in claim 19, wherein the predetermined wavelength is approximately 980 nm.

Serial No. 10/766,172  
Page 7 of 11

Docket No. INSC-109.4

31. (Original) A stopper as defined in claim 19, wherein the predetermined power is less than approximately 30 Watts.

32. (Original) A stopper as defined in claim 31, wherein the predetermined power is less than or equal to about 10 Watts.

33. (Original) A stopper as defined in claim 19, wherein the pigment is gray.

34. (Original) A stopper as defined in claim 33, wherein the amount of pigment is within the range of about 0.3% to about 0.6% by weight.

35. (Original) A stopper as defined in claim 19, wherein the predetermined time period is less than about 1 second.

36. (Original) A stopper as defined in claim 19, wherein the lubricant is selected from the group including silicone, mineral oil, and silicone oil.

37. (Original) A stopper as defined in claim 19, wherein the lubricant is silicone oil and the amount of lubricant is within the range of about 0.4 to about 0.6% by weight.

Serial No. 10/766,172  
Page 8 of 11

Docket No. INSC-109.4

38. (Original) A stopper as defined in claim 19, in combination with a needle for penetrating the stopper, wherein the needle includes a non-coring, conically-pointed tip defining an included angle within the range of about 15 degrees to about 25 degrees.

39. (Original) A stopper and needle as defined in claim 38, wherein the needle includes a low-friction exterior surface for reducing friction forces between the needle and stopper during penetration thereof.

40. (Original) A stopper and needle as defined in claim 17, wherein the low-friction surface is selected from the group including a tungsten carbide surface, an electro-polished stainless steel surface, and a titanium surface.

41. (Currently Amended) A method of providing and filling a container with a predetermined substance/medicament, comprising the following steps:

providing a thermoplastic stopper defining a needle penetration region that is pierceable with a needle to form a needle aperture therethrough, and is heat resealable to hermetically seal the needle aperture by applying laser radiation at a predetermined wavelength and power thereto, wherein the stopper further includes a thermoplastic body defining a predetermined wall thickness in an axial direction thereof, and includes a styrene block copolymer and an olefin;

providing the thermoplastic stopper with a predetermined amount of pigment that allows the body to substantially absorb laser radiation at the predetermined wavelength and substantially prevent the passage of radiation through the predetermined wall thickness thereof;

Serial No. 10/766,172  
Page 9 of 11

Docket No. INSC-109.4

connecting the stopper to an opening end of a containervial and defining a sealed chamber between the stopper and containervial;

providing a needle defining a non-coring, conically-pointed tip and at least one flow aperture located adjacent to the tip and connectable in fluid communication with a source of the predetermined substancemedicament;

penetrating the needle penetration region of stopper with the conically-pointed tip of the needle such that the flow aperture of the needle is in fluid communication with the chamber of the containervial;

providing a lubricant at the interface of the needle and stopper to reduce friction forces therebetween;

introducing the predetermined substancemedicament through the needle and into the chamber of the containervial, and withdrawing the needle from the stopper; and

transmitting laser radiation at the predetermined wavelength and power onto the needle penetrated region of the stopper, and hermetically sealing the needle aperture formed in the needle penetration region thereof in a time period of less than about 2 seconds.

42. (Original) A method as defined in claim 41, wherein the step of providing a lubricant includes providing within the stopper body a predetermined amount of lubricant that reduces friction forces at the interface of the needle and stopper.

43. (Currently Amended) A method as defined in claim 41, further comprising the steps of molding the stopper and containervial body from plastic under a substantially laminar flow;

Serial No. 10/766,172  
Page 10 of 11

Docket No. INSC-109.4

and prior to allowing the stopper and container~~vial~~ body to cool to an ambient temperature, assembling the stopper and container~~vial~~ body and forming a sealed, sterile and pyrogen free chamber therebetween.

44. (Original) A method as defined in claim 41, further comprising the step of transmitting e-beam radiation onto the surface of the needle prior to penetrating the stopper therewith.

45. (Original) A method as defined in claim 41, further comprising the step of transmitting e-beam radiation onto the stopper during laser sealing thereof.

46. (New) A method as defined in claim 41, wherein the step of introducing includes introducing medicament.

47. (New) A method as defined in claim 41, wherein the step of connecting the stopper to an opening of a container includes connecting the stopper to an open end of the container forming a vial.